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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,669

Applicant(s)

WANG ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 8,10 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title include HpyCII, the name of the restriction endonuclease of the instant application

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims do not indicate the intervention of "the hand of man", which is required for patent claims in the U.S., and read on the enzyme as it occurs in nature. The "recombinant enzyme" of claim 13 also reads on the enzyme as it occurs in nature since all proteins in nature are recombinant to some degree. Adding "isolated" or some similar phrase would overcome this rejection.

Claims 1-2, 4-7, 9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incorrect in the recitation of "comprising" and "recognizing and cutting", which should apparently be "comprises the" and "recognizes and cuts".

Claim 1 is incorrect in the recitation of "SEQ ID No: 3". The correct recitation is "SEQ ID NO:3".

Claim 2 is incorrect in the recitation of "is from bioorganism", which should be "is from a bioorganism"

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Claims 4 and 5 are incorrect in the recitation of "SEQ ID NO : 1". The correct recitation is "SEQ ID NO:1".

Claim 5 does not further limit claim 1 and therefore does not comply with the requirements of 35 USC § 112 fourth paragraph. Claim 1 requires that the enzyme cut "at a particular sequence of nucleotides" and claim 5 requires that the enzyme cut "downstream of said DNA sequence of nucleotides".

Claims 5 and 13 are confusing and indefinite in the recitation of "upper strand" and "lower strand". What is the upper strand and what is the lower strand is entirely dependent upon the orientation of the DNA and DNA changes orientation constantly. A better way of describing this phenomenon is required such as giving the recognition sequences in both strands of the DNA and stating how many base pairs downstream from each the enzyme cleaves or drawing the DNA sequence with the cleavage point indicated.

Claim 6 is incorrect in the recitation of "derived from microorganism", which should be "derived from a microorganism"

Claims 7 is incorrect in the recitation of "the microorganism are...", which should be "the microorganism is..."

Claim 9 is incorrect in the recitation of "sequence having the", which should be "sequence has the". The claim is also incorrect in the recitation of "SEQ ID NO : 2", which should be "SEQ ID NO:2".

Claim 12 is incorrect in the recitation of "comprisings", which should be "comprising".

Claim 13 is incorrect in the recitation of "SEQ ID NO : 3". The correct recitation is "SEQ ID NO:3".

Claim 13 is incorrect in the recitation of "specifically recognizing... and cleaves". The tenses of the verbs do not correspond. Either the reci-

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tation should be "that specifically recognizes...and cleaves" or else "specifically recognizing...and cleaving"

Claim 13 is also apparently incorrect in the recitation of "composing" on line 4, which should apparently be "comprising".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims state that the restriction endonuclease "cleaves DNA downstream...at the fourth base in the upper strand and the fifth base in the lower strand". This is also stated in paragraph 34 as well as other places in the specification. To start with, "upper strand" and "lower strand" are confusing as what is upper and what is lower is entirely dependent upon how the DNA is oriented. Looking at Table 1, the first position shown (1325-1364) cleaves after the fourth base pair downstream (towards the 3' end) of the strand. The second position shown (1596-1635) shows the inverse complement of the recognition sequence and it cleaving after the fourth base upstream from this recognition site. The third position (4797-4836) shows again the inverse complement of the recognition sequence and it cleaving after the fifth base pair upstream. This is apparently not what is in the

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instant claims and one of ordinary skill in the art would not be taught exactly where the enzyme cleaves. An explanation is required.

Claims 8 and 10-11 are objected to as being dependent upon a rejected base claim.

No art rejection is being made. After a search of the prior art the examiner can find nothing that would anticipate or make obvious the instant claims. All of the restriction endonucleases found for *Helicobacter pylori* in the prior art either have a different sequence from SEQ ID NO:3 and/or the recognition sequence is different.

Morgan, et al. (A-F), Aras, et al. (U) and Lin, et al. (V) are cited as of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

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Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
April 18, 2006